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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,466

10/21/2003

Liping Tang

UTAR:1023

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03/31/2009

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EXAMINER

BAEK, BONG-SOOK

ART UNIT

PAPER NUMBER

1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/690,466	Applicant(s) TANG ET AL.	
	Examiner BONG-SOOK BAEK	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/3/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

The amendment filed on February 11, 2009 is acknowledged. Claims 1-8 and 13-27 have been canceled. Claims 9-12 are currently pending and under examination in the instant office action.

Applicants' arguments filed on February 11, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed on 11/3/2008 is enclosed in this action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hoffman (Clinical Chemistry, 46: 1478-1486, 2000) in view of US 2003/0138490 A1 (pub. date: 7/24/2003, effective US filing date: 8/9/2001).

The instant invention is drawn to a functionalized particle comprising:
a functionalized particle, wherein the particle is selected from the group consisting of hydroxypropyl cellulose, N-isopropylacrylamide, and hyaluronan and a functionalized portion is a nitrogen-containing functional group (preferably hydrazide or an amine), wherein the functionalized portion is directly associated with a tag (preferably antibody), and wherein the particle is less than 1.0 mm in diameter; and the tag is in contact with the functionalized particle.

Hoffman teaches that smart polymer such as poly (N-isopropyl acrylamide) and hydroxypropy cellulose physically mixed with or chemically conjugated (directly associated) to biomolecules (tag) such as antibodies (abstract; p1478 2nd paragraph, p1479, 2nd paragraph; and table 2). Hoffman further teaches the lysine amino groups (amine) are the most reactive sites (functionalized portion) for random polymer conjugated to proteins, and N-succinimide attachment chemistry is commonly used (p1479, 1st paragraph).

Since the instant invention is directed to a composition, an intended use recited in the instant claim 11 (for ocular disease), does not have a patentable weight. In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

The reference differs from the instant claims insofar as it does not specifically teach that the particle is less than 1.0 mm in diameter.

US 2003/0138490 A1 teaches a nanostructured polymeric materials comprising nanoparticle containing polymers such as hydroxypropyl cellulose or N-isopropylacrylamide in a particle size range of 1-1000 nanometer, preferably 1-500 nanometers in diameter ([0057], and claims 5-7) and at least one pharmaceutically active compound for drug delivery (claims 11 and 13). US 2003/0138490 A1 further teaches a nanostructured gel provides useful improvements in a variety of technological applications including controlled delivery of drugs or active agents ([0012])

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make the bioconjugate comprising smart polymer and biomolecules such as antibodies taught by Hoffman into the particle less than 1.0 mm in diameter with a reasonable expectation of success because of the following reasons: As stated above, Hoffman teaches the particle comprising a smart polymer such as N-isopropylacrylamide or hydroxypropyl cellulose

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conjugated with a tag such as antibody in contact with the functionalized portion, which may have many interesting applications in diagnostics, affinity separations, drug delivery, delivery of chemical or biochemical reagents in a process reaction, and signal transduction (p1485, 1st paragraphs and table 4). US 2003/0138490 A1 teaches a nanoparticle comprising the same polymer with a bioactive agent and further teaches that the nanostructure provides advantageous improvements for technological applications such as controlled delivery of drugs or active agents. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to reduce the particle size to less than 1.0 mm in diameter in order to improve biocompatibility for various pharmaceutical applications.

Response to Applicants' arguments:

In response to the argument that the cited reference fails to demonstrate "a functional nitrogen group", the teaching of Hoffman that the lysine amino group of the random polymer is the most reactive sites for conjugation with proteins (tag) and N-succinimide attachment chemistry is commonly used encompasses the claimed functional nitrogen group since the amino acid is an amine, which is one of examples of the functionalized portion recited in the instant claim 12 as stated in the previous action mailed on 9/12/2008.

With regard to lack of sufficient teaching of how to make the present invention in the prior art, the prior art actually discloses sufficient information about how to make the claimed bioconjugate by known methods. For instance, Hoffman teaches that the bioconjugates have been prepared by random polymer conjugation or site-specific conjugation (abstract). It further states that they have been able to make polymer-biomolecule conjugates by site-specific

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conjugation to –SH thiol group or –NH₂ group (p1479, column2, para 2 and figures 3 and 4).

Thus, one of ordinary skill in the art would be able to make and use the claimed invention by the methods disclosed in the prior art.

The rejection of Claim 9-12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 16-20 of copending Application No. 11/660,282 is withdrawn since a terminal disclaimer has been filed. However the following double patenting rejection is maintained because applicant has not filed a terminal disclaimer and presented no argument.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8, 10, 15-17, 19 and 33 of copending Application No. 10/896,376 ('376 hereinafter) in view of Hoffman. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the copending application are drawn to a particle preparation comprising N-isopropylacrylamide and a tag. The claims of '376 does not recite a nitrogen-containing functional group and antibody as a tag, however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to identify the nitrogen-containing functional group as a functionalized portion and to use an antibody as a tag in view of the teachings of Hoffman as stated above in 103 rejection. In addition, the instant claims do not recite a surfactant which is recited in the '376 claims, however the instant claims recite the open language "comprising", which does not exclude additional unrecited elements (see MPEP 2111.03).

This is provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

No new ground(s) of rejection has been presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
Bbs

BONG-SOOK BAEK
Examiner, Art Unit 1614